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FACT SHEET

The New Science of LASIK

- There are two steps in the LASIK procedure and new science reveals that the first step – creating a corneal flap – has been overlooked for its affect on the visual outcome of the procedure.

- When LASIK surgeons began using the IntraLase® femtosecond (fem-tō-second) laser for corneal flap creation, they noticed a marked improvement in patient vision. The IntraLase laser, designed to decrease complications in LASIK's first step, was also providing better visual outcomes.
  - *Historically, LASIK's first step was employed with a hand-held oscillating surgical blade, called a microkeratome. While LASIK is a successful and relatively safe procedure, the microkeratome causes the majority of severe, sight-threatening complications.*

- New clinical data reveal the IntraLase FS laser does more than create a safer, planar corneal flap. It also prepares an optimal corneal surface below the flap, providing for superior visual outcomes, especially among Custom/Wavefront patients.

  Editor's Note: Wavefront is a map of the eye's surface indicating the minute high and low spots which affect crispness and clarity of vision.
  - It is well documented that Custom LASIK has not fully met doctors' expectations for better outcomes and reduced higher-order aberrations. This is what the IntraLase laser delivers. (Durrie, Manche, Tran)
  - Data show the IntraLase laser helps Custom LASIK deliver on its promise of better visual outcomes beyond 20/20 to 20/15 and 20/12.5. (Manche, Schallhorn, Durrie)
  - Prospective, randomized evaluation of wavefront aberrations shows the IntraLase laser induces fewer higher- and lower-order aberrations (associated with night glare and halos), allowing for a corneal surface consistent with wavefront recordings taken pre-operatively. (Tran)
    - *If the corneal surface is left with microscopic high and low spots, the precision of the excimer tissue ablation (step two) can be compromised. Eliminating even minute inaccuracies on the corneal surface improves the visual outcome of the procedure.*
  - A greater number of standard-LASIK patients also achieve visual results better than 20/20 with IntraLase-initiated LASIK. (Sloane, Durrie, Manger)
  - The intentional planar architecture of the IntraLase flap and corneal bed, created with micron-level precision, significantly reduces the incidence of post-operative induced astigmatism – a microkeratome complication that occurs with some frequency. (Kezirian, Stonecipher)
  - Patients with a preference in prospective, randomized clinical trials chose the post-operative vision of their IntraLase-treated eye up to 3-to-1 over their blade-treated eye. (Durrie, Manche)

Advantages of the IntraLase FS laser

Better Vision: Patients achieve statistically better vision with IntraLase-initiated LASIK. (Durrie, Schallhorn)

Improved Safety: Virtually eliminates the severest LASIK complications.

Fewer Retreatments: The number of LASIK retreatments (enhancements) required to perfect the visual outcome is significantly lower. (Manger)

Reduced Dry Eye Symptoms: In clinical studies, standard tests performed to diagnose dry eye show a reduction in symptoms by as much as 72 percent. (Christenbury)

Highest Degree of Predictability and Precision: Preserves corneal tissue with reproducible flap thickness within ± 10 microns, compared to reported variability of up to ± 40 microns with microkeratomes. (Binder)

Thinner Flaps: Patients previously contraindicated for LASIK due to thin corneas may now be candidates.

Technology of Choice: The IntraLase laser has become the technology of choice among the nation's leading LASIK surgeons and ophthalmic teaching institutions.

(more)

How the IntraLase FS30™ Laser Works

The ultra-fast IntraLase FS30 laser uses an infrared light beam, generating 30,000 pulses per second, to prepare the intracorneal bed and create the corneal flap in the first step of LASIK.

- Using an "inside-out" process, the laser beam is precisely focused to a point within the cornea.
- The laser pulses then create thousands of microscopic bubbles which define the precise architecture* of the intracorneal surface, as well as the distinct beveled edge of the resulting flap.
- Along the edge bubbles are then stacked up to the corneal surface to complete step one.
- From start to finish, the IntraLase process takes approximately 30 seconds.
- The physician then exposes the prepared corneal bed for excimer laser treatment (the second step of LASIK) by lifting the flap.
- The LASIK procedure is complete when the flap is securely repositioned on its beveled edge.

*With the IntraLase laser, the surgeon can precisely control the critical first step of LASIK. Physician-programmed laser specifications include flap diameter, depth, hinge location and width, and side-cut architecture – factors which can be varied to meet patients' needs. The IntraLase laser creates a distinctive beveled edge flap, which allows for precise repositioning, alignment and seating after LASIK is completed. This feature reduces the risk of flap displacement, a complication seen with microkeratome flaps.

- The IntraLase laser drives superior visual outcomes by optimizing the intra-corneal surface for refractive procedures like LASIK. Computer-guided technology provides for the highest-precision surgical control.
- The IntraLase laser is the only laser technology available today for use in the first step of the LASIK procedure. It delivers micron-level accuracy more than 100 times greater than a microkeratome. (Wang)

Making LASIK Safer

- The IntraLase laser makes LASIK safer by replacing the hand-held microkeratome blade with the silent computer-guided precision of a laser, virtually eliminating severe sight-threatening blade-related LASIK complications as a result. (Binder)
- Data confirm that the IntraLase laser is dramatically less likely to produce seriously thin flaps or extremely thick flaps, events that could lead to devastating complications. (Wang)
- The use of the IntraLase laser improves the overall safety profile and visual results of LASIK, be it Custom or standard. (Binder, Durrie, Schallhorn)
- When given a choice, 78 percent of patients choose IntraLase-initiated LASIK rather than the blade. (SM2 Consulting)
- Physician reports on more than 250,000 IntraLase corneal flap procedures performed globally by leading LASIK surgeons demonstrate an impressive safety profile:
  - NO deep, invasive corneal incisions
  - Partial, improperly formed, free or buttonhole flaps and corneal abrasions practically eliminated.
- Microkeratome complications occur in up to 10 percent of all LASIK procedures, including the most serious complications that may affect the visual outcome of a LASIK procedure. The most common complications include buttonhole cuts, partial or improperly formed flaps, free caps, invasive corneal incisions, corneal abrasions, and subsequently blurred vision (Ambrosio and Wilson, Osman).